

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2666
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Medicaid VBPs for
3 Patients Act” or the “MVP Act”.

**4 SEC. 2. CODIFYING VALUE-BASED PURCHASING ARRANGE-
5 MENTS UNDER MEDICAID AND REFORMS RE-
6 LATED TO PRICE REPORTING UNDER SUCH
7 ARRANGEMENTS.**

8 (a) CODIFYING MULTIPLE BEST PRICE POINTS.—

9 (1) IN GENERAL.—Section 1927(c)(1)(C)(ii) of
10 the Social Security Act (42 U.S.C. 1396r-
11 8(c)(1)(C)(ii)) is amended—

12 (A) in subclause (IV), by striking “and” at
13 the end;

14 (B) in subclause (V), by striking the period
15 and inserting “; and”; and

16 (C) by adding at the end the following new
17 subclause:

1 “(VI) may include multiple best
2 price points for a single dosage form
3 and strength of a drug of a manufac-
4 turer subject to a value-based pur-
5 chasing arrangement (as defined in
6 subsection (k)(12)), but only if such
7 manufacturer offers such arrangement
8 to all States.”.

9 (2) RULE OF CONSTRUCTION.—Nothing in the
10 amendments made by this subsection may be con-
11 strued to prohibit a manufacturer from treating a
12 value-based purchasing arrangement as a bundled
13 sale.

14 (b) DEFINITION OF AVERAGE MANUFACTURER
15 PRICE.—

16 (1) IN GENERAL.—Section 1927(k)(1) of the
17 Social Security Act (42 U.S.C. 1396r-8(k)(1)) is
18 amended—

19 (A) in subparagraph (B)(i)—

20 (i) in subclause (VII), by striking at
21 the end “and”;

22 (ii) in subclause (VIII), by striking
23 the period at the end and inserting “;
24 and”; and

1 (iii) by adding at the end the fol-
2 lowing new subclause:

3 “(IX) with respect to such cov-
4 ered outpatient drug that is sold
5 under a value-based purchasing ar-
6 rangement (as defined in paragraph
7 (12)) during the rebate period, includ-
8 ing such drug that is an inhalation,
9 infusion, instilled, implanted or
10 injectable drug that is not generally
11 dispensed through a retail community
12 pharmacy—

13 “(aa) a refund, rebate, reim-
14 bursement, or free goods from
15 the manufacturer or third party
16 on behalf of the manufacturer; or

17 “(bb) the withholding or re-
18 duction of a payment to the man-
19 ufacturer or third party on behalf
20 of the manufacturer;

21 that is triggered by a patient who
22 fails to achieve outcomes or measures
23 defined under the terms of such value-
24 based purchasing arrangement during

1 the period for which such arrange-
2 ment is effective.”; and

3 (B) by adding at the end the following new
4 subparagraph:

5 “(D) SPECIAL RULE FOR CERTAIN VALUE-
6 BASED PURCHASING ARRANGEMENTS.—For
7 purposes of subparagraph (A), in determining
8 the average price paid to the manufacturer for
9 a covered outpatient drug that is sold under a
10 value-based purchasing arrangement (as defined
11 in paragraph (12)) that provides that payment
12 for such drug is made in installments over the
13 course of such agreement, such price shall be
14 determined as if the aggregate price per the
15 terms of the agreement was paid in full in the
16 first installment during the rebate period.”.

17 (2) GUIDANCE.—Not later than 180 days after
18 the date of the enactment of this Act, the Secretary
19 of Health and Human Services shall issue guidance
20 to State Medicaid agencies on the implementation of
21 the amendments made by this subsection.

22 (c) DEFINITION OF VALUE-BASED PURCHASING AR-
23 RANGEMENT.—Section 1927(k) of the Social Security Act
24 (42 U.S.C. 1396r-8(k)) shall be amended by adding at the
25 end the following paragraph:

1 “(12) VALUE-BASED PURCHASING ARRANGE-
2 MENT.—The term ‘value-based purchasing arrange-
3 ment’ has the meaning given such term in section
4 447.502 of title 42, Code of Federal Regulations (or
5 an successor regulation).”.

6 **SEC. 3. CALCULATION OF AVERAGE SALES PRICE UNDER**
7 **MEDICARE.**

8 Section 1847A(c)(3) of the Social Security Act (42
9 U.S.C. 1395w-3a(c)(3)) is amended—

10 (1) by striking “In calculating” and inserting
11 the following:

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), in calculating”; and

14 (2) by adding at the end the following new sub-
15 paragraph:

16 “(B) CERTAIN REBATES UNDER VALUE-
17 BASED PURCHASING ARRANGEMENTS EX-
18 CLUDED.—In calculating the manufacturer’s
19 average sales price under this subsection for a
20 drug or biological that is sold under a value-
21 based purchasing arrangement (as defined in
22 section 1927(k)(12)) and with respect to which
23 the manufacturer of such drug or biological has
24 elected to include multiple best price points (as
25 described in section 1927(c)(1)(C)(ii)(VI)) in

1 reporting the best price of such drug under sec-
2 tion 1927(b), such price shall not include any
3 rebate that is triggered by a patient who fails
4 to achieve outcomes or measures defined under
5 the terms of such arrangement during the pe-
6 riod for which such arrangement is effective.”.

7 **SEC. 4. GUIDANCE ON VALUE-BASED PURCHASING AR-**
8 **RANGEMENTS FOR INPATIENT DRUGS UNDER**
9 **MEDICAID.**

10 Not later than 180 days after the date of the enact-
11 ment of this Act, the Secretary of Health and Human
12 Services shall issue guidance to State Medicaid agencies
13 on the option of entering into a value-based purchasing
14 arrangement (as defined in section 1927(k)(12) of the So-
15 cial Security Act (42 U.S.C. 1396r–8(k)(12))) with manu-
16 facturers for drugs or biological products provided as part
17 of, or as incident to and in the same setting as, inpatient
18 hospital services furnished under a State plan under title
19 XIX of the Social Security Act (42 U.S.C. 1396 et seq.),
20 or under a waiver of such plan, where such drugs or bio-
21 logical products are reimbursed directly and not paid for
22 as part of payment for such inpatient hospital services,
23 including guidance on how multiple States may enter into
24 agreements with one another and with manufacturers
25 which permit the transfer of funds between the partici-

1 pating States so that individuals who reside in a State
2 different from the State in which they receive a drug sub-
3 ject to an value-based purchasing arrangement as an inpa-
4 tient may be treated as if they received such drug in the
5 State in which they reside.

6 **SEC. 5. EXCEPTION UNDER THE ANTIKICKBACK STATUTE.**

7 (a) IN GENERAL.—Section 1128B(b)(3) of the Social
8 Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

9 (1) in subclause (J), by moving the left margin
10 of such subparagraph 2 ems to the left;

11 (2) in subclause (K)—

12 (A) by moving the left margin of such sub-
13 paragraph 2 ems to the left; and

14 (B) by striking “and” at the end;

15 (3) in subparagraph (L)(iii), by striking the pe-
16 riod and inserting “; and”; and

17 (4) by adding at the end the following new sub-
18 paragraph:

19 “(M) any remuneration provided by a
20 manufacturer or third party on behalf of a
21 manufacturer to a State under a value-based
22 purchasing arrangement (as defined in section
23 1927(k)(12)) under a State plan under title
24 XIX (or waiver of such plan) in the case a pa-
25 tient fails to achieve outcomes or measures de-

1 fined in such arrangement following the admin-
2 istration of a covered outpatient drug (as de-
3 fined in section 1927(k)(2)).”.

4 (b) RULEMAKING.—Not later than 180 days after the
5 date of the enactment of this Act, the Inspector General
6 of the Department of Health and Human Services shall
7 through rulemaking implement the amendments made by
8 this section.

9 **SEC. 6. GAO STUDY AND REPORT ON USE OF VALUE-BASED**
10 **PURCHASING ARRANGEMENTS.**

11 (a) STUDY.—The Comptroller General of the United
12 States shall conduct a study on the extent to which value-
13 based purchasing arrangements (as defined in section
14 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r-
15 8(k)(12)) facilitate patient access to covered outpatient
16 drugs, improve patient outcomes, lower overall health sys-
17 tem costs, and lower costs for patients in Federal health
18 care programs. In conducting such study, the Comptroller
19 General shall—

20 (1) study the impact of this Act on—

21 (A) access to transformative therapies, in-
22 cluding rare disease gene therapies, generally;

23 (B) mitigating socioeconomic disparities in
24 accessing covered outpatient drugs sold under
25 value-based purchasing arrangements through

1 its requirement that State Medicaid programs
2 have access to the same value-based purchasing
3 arrangement pricing structure that are available
4 in the commercial market for such drugs;

5 (C) the Medicaid drug rebate program
6 under section 1927 of the Social Security Act
7 (42 U.S.C. 1396r-8), the 340B drug pricing
8 program under section 340B of the Public
9 Health Service Act (42 U.S.C. 256b), and part
10 B of title XVIII of the Social Security Act (42
11 U.S.C. 1395j et seq.), including compliance
12 with such programs;

13 (D) expenditures under State Medicaid
14 programs; and

15 (E) prices for such drugs under the Med-
16 icaid program in States that do not enter into
17 such arrangements;

18 (2) analyze all the types of value-based pur-
19 chasing arrangement pricing structures, which struc-
20 tures are working well (as measured by price and
21 ease of implementing), and which need improvement;
22 and

23 (3) study the potential long-term savings for
24 States that enter into such arrangements under
25 State Medicaid programs.

1 (b) REPORT.—Not later than June 30, 2028, the
2 Comptroller General of the United States shall submit to
3 Congress a report containing the results of the study con-
4 ducted under subsection (a).

